No. 77-956

IN THE

Supreme Court of the United States

OCTOBER TERM, 1977

PARKE, DAVIS & COMPANY,
Petitioner,

v.

JOSEPH A. CALIFANO, Secretary of Health, Education, and Welfare, *et al.*,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Sixth Circuit

REPLY BRIEF FOR PETITIONER

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March 13, 1978

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A few fundamental matters merit brief reply in view of respondents' attempt at obfuscation:

1. Benylin was lawfully on the over-the-counter market under the regulations of the Food and Drug Administration,[1] and had previously been lawfully marketed

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[1] 41 Fed. Reg. 32580, Pet. App. 51a. Contrast Brief in Opposition (p. 5 and n.6) with the plain language of the regulation authorizing the OTC marketing of Benylin:

> "2. Any such drug product may be marketed after the date of publication of a proposed monograph in the FEDERAL REGISTER, but before the effective date of a final monograph, subject to the risk that the Commissioner may not accept a panel's recommendation but adopt a different position that could require relabeling, recall, or other regulatory action."

See also Pet. at 5-6.

OTC in accordance with informal FDA policy.[2] If that had not been so, FDA would not have taken the position in November 1976 that its actions caused "the marketing status" of Benylin to "rever[t] . . . to prescription sale" (Pet. App. 102a). Alternatively, if the government seriously contends that a drug cannot lawfully be marketed OTC after a panel's proposed monograph is published without dissent, resolution of this issue by this Court is needed because of its significance to the on-going OTC Review program. Many other drugs would be affected, and much other litigation could be provoked, if the issue is not now resolved.

2. Parke-Davis is entitled to a hearing on whether Benylin can be sold OTC or must be restricted to prescription sale, and that hearing has been held. But it is idle speculation at best and highly misleading at worst for respondents to "expect the agency to complete all its proceedings in this matter by April 1978" (Br. Op. at 6, n.8), less than one month from now. The Administrative Law Judge has yet to render an initial decision; after that there is normally a 30 day period for the filing of exceptions with the FDA Commissioner, 21 C.F.R. § 12.125 (a); and then there is no limit on how long the Commissioner might take to rule.[3]

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[2] Respondents' denigrating reference to "an FDA attorney, Gary Yingling" (Br. Op. at 4) hides the fact that Mr. Yingling was the Associate Chief Counsel for Enforcement; that he was writing on behalf of the agency; and that the "*de facto* approval" (Pet. App. 17a) granted by his letter was in accordance with FDA practice at the time. *See* Pet. at 5, n.5. Moreover, his letter was in response to Parke-Davis' February 28, 1975 letter to FDA which requested approval of OTC marketing of Benylin and which specifically noted that FDA's Bureau of Drugs had accepted the cough-cold expert panel's recommendations with respect to Benylin (JA 20a).

[3] In addition, in a Freedom of Information Act case brought by Parke-Davis seeking documents relating to DPH, the district judge on March 7, 1978 ordered the government to produce withheld documents for in camera inspection. ***Parke, Davis & Company*** v.

3. Respondents do not question that Parke-Davis will suffer irreparable injury if Benylin is now restricted to prescription sale and the administrative hearing eventually concludes that Benylin is suitable for OTC sale. Nor do respondents contend that any health hazard is involved in OTC sale of Benylin.

4. Respondents conveniently ignore the fact that the seizures of Benylin took place after this lawsuit was filed; and they carefully fail to deny that their representatives did not tell the district judge that seizures were planned when the hearing on Parke-Davis' request for preliminary relief was postponed. *Compare* Pet. at 6-7 *with* Br. Op. at 7, n.9. It was the initiation of seizure actions in violation of the understanding to maintain the status quo that the district judge characterized as "dirty pool." Tr. of Dec. 1, 1976 Hearing at 22.

5. Respondents interpret *Ewing* to preclude district courts from enjoining FDA enforcement actions (Br. Op. at 9). If that were so, there would be nothing left of *Abbott Laboratories*, which held that preenforcement review (and injunctions against enforcement actions) are available where, as here, the challenged agency action has a direct and immediate impact on the company; the issue presented is a straight-forward legal one; and the failure to rule would put the company to the dilemma of either complying with the agency's allegedly invalid instructions (at great expense and business harm) or risking a later government enforcement action.[4] See Pet.

Califano, Civil Action No. 77-2813 (E.D. Mich.). The Administrative Law Judge has already indicated that if Parke-Davis obtains additional pertinent documents, the agency proceeding could be reopened. Transcript at 1001, *In re Benylin Expectorant: Proposal to Deny Approval of Supplemental New Drug Application* (FDA Dkt. No. 76N-0483).

[4] Contrary to Respondents' contention (Br. Op. at 10-11), *Abbott Laboratories* does not turn on the number of companies affected by the challenged agency action. In any event, the FDA's decision

at 10-11, 15. *Ewing*, in contrast, involved an attempt to review the factual basis for one of the early steps in the enforcement decision-making process, a step that had no impact on the plaintiff in and of itself. Thus *Ewing* is inapplicable whether the holding of the district court is narrowly (but incorrectly) characterized as restraining merely a decision to institute seizure (Br. Op. at 8) or as enjoining an arbitrary and capricious course of conduct, as the district court explained (Pet. at 7-8). Parke-Davis is simply asking for the same result here as that which obtained in the *Bentex* case, and respondents' mechanical observation that the propriety of the injunction granted there was not even challenged by the government on appeal, is no answer at all.

6. Respondents advance no policy argument as to why Parke-Davis should be limited to the subsequent seizure actions for the judicial review to which it is admittedly entitled, instead of having preenforcement review in this action. If it is true, as respondents repeatedly say, that every issue raised here is available in the enforcement action (Br. Op. at 8, 12), then it makes no sense to call a halt to this case, which was filed first. The district court had jurisdiction (Pet. App. 13a, 18a); FDA could and did oppose the relief Parke-Davis sought; and FDA could have sought an injunction itself. Thus permitting preenforcement review would cause FDA no harm. Forcing Parke-Davis to await the enforcement action, on the other hand, not only maximizes its uncertainty about the propriety of its operations, but also keeps the company from litigating until after the FDA has removed its product from the market. Finally, to accept respondents' sterile argument would be to consign the doctrine of

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to force drugs containing DPH to revert to a prescription basis without a hearing was applicable by its terms not just to Benylin, but to "any product marketed containing [DPH] for OTC antitussive use". Decision on Diphenhydramine As An Antitussive, 41 Fed. Reg. 52536 (November 30, 1976).

Abbott Laboratories to limbo. For every time preenforcement review is sought—in an FDA case or in a case involving any other federal agency—the alternative is to challenge the agency later in whatever kind of enforcement action it is permitted to bring. That fact was not dispositive in *Abbott Laboratories*, and it is not dispositive here.

CONCLUSION

For the reasons stated in the Petition and this Reply, the Petition for Certiorari should be granted.

Respectfully submitted,

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